

REMARKS

The Applicants request the entry of the amendments to the Claims. Applicants request that Claims 1-7 and 9-18 be cancelled. Applicants request the amendment of Claims 8, 19, and 21, and the entry of new Claims 24-35.

Claim 8 is being amended to more clearly specify that the composition of the claim is a veterinary pharmaceutical composition that is effective for controlling parasites that live on or in a mammal. Prior to the amendment, the composition of Claim 8 contained the compounds of Claim 1. Because Claim 1 is being cancelled, the limitations of Claim 1 are being placed inside amended Claim 8.

New Claims 31-35 are dependent on Claim 8 and more clearly define the compounds in the veterinary pharmaceutical composition.

Claim 19 is being amended to recite that the method of treating a mammal (rather than an animal) for parasites that live in or on the mammal by administering the veterinary pharmaceutical compositions of Claim 8 to the mammal.

Claim 21 is being amended to include the phrase "veterinary pharmaceutical" prior to "composition".

Claim 24 is being added to further limit Claim 22 to nematodes and trematodes.

Claims 25 is being added to cover a method of controlling parasites that live on or in a mammal by administering to the mammal the veterinary pharmaceutical composition of Claim 8. This claim is similar to cancelled Claim 10 yet refers to the veterinary pharmaceutical composition of Claim 8 rather than the compounds of Claim 1 which is cancelled. Claims 26-29 are dependent on Claim 25.

Support for the amendments and the new claims can be found throughout the Specification. In particular, the definition of the compounds within the veterinary pharmaceutical compositions are found on pages 1-9. The description of compositions containing these compounds are on pages 16-27. The method of treating a mammal for parasites and the method of controlling parasites living on or in a mammal are discussed on pages 13-16 and 36-39. No new matter is being added.

35 U.S.C. § 112, second paragraph

The Examiner rejected Claim 7 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

The Applicants are canceling Claim 7. As such, this rejection is moot. The Applicants request that the Examiner withdraw this rejection.

35 U.S.C. § 102(b)

The Examiner rejected Claims 1-5, 8, 10, 13-14, and 16 under 35 U.S.C. § 102(b) as being anticipated by Andoh et al. (U.S. Patent 6,239,077). The Examiner noted that Andoh et al. discloses compounds and compositions containing the some of the same compounds and compositions as the Applicants claim.

The Applicants have cancelled Claims 1-5, 10, 13-14, and 16. The Applicants are not requesting new method claims that depend on the compounds of formula (I). Rather, the new method claims depending on veterinary pharmaceutical compositions that contain the compounds of formula (I) which was the subject matter of cancelled Claim 10 and is now in new Claim 25.

As such, Applicants will discuss how new Claim 25 and claims dependent on Claim 25 are novel in light of Andoh et al. The Applicants will also discuss below how Claim 8 is not disclosed by Andoh et al.

Claim 8 covers veterinary pharmaceutical compositions containing at least one compound of formula (I) and carriers and/or diluents whereby the compositions kill parasites that live on or in a mammal when applied to the mammal.

In contrast, Andoh et al. discloses compounds and compositions containing those compounds that are applied to plants and to soil and that are effective at killing pests on plants and soil. Andoh et al. fails to disclose veterinary pharmaceutical compositions containing compounds of formula (I) that are applied to a mammal and are effective at killing parasites that live on or in the mammal. Andoh et al. fails to disclose that the compositions disclosed in Andoh et al. can be applied to a mammal and fails to disclose that the compositions would kill a parasite that lives on or in the mammal. As such, Andoh et al. fails to disclose all of the elements of Claim 8.

New Claim 25 and its dependent claims cover methods of controlling parasites that live on or in a mammal by applying compositions containing compounds of formula (I) to the mammal.

In contrast, Andoh et al. discloses method of killing pests that live on plants or in soil by applying to plants and/or to soil compositions containing certain compounds. Andoh et al. discloses that the compositions when applied to plants and/or soil kill the pests that live in the soil and/or on the plant. However, Andoh et al. fails to disclose methods of controlling parasites that live on or in a mammal by administering veterinary pharmaceutical compositions containing

at least one compound of formula (I) to the mammal. Andoh et al. fails to disclose that the compositions can be applied to a mammal and fails to disclose that the compositions would kill a parasite that lives on or in the mammal. As such, Andoh et al. fails to disclose all of the elements of Claim 25 and the dependent claims.

As such, Applicants believe that this 102(b) rejection is inappropriate and requests withdrawal of the rejection.

35 U.S.C. § 103(a)

The Examiner rejected Claims 1-6, 8, 10, and 13-23 under 35 U.S.C. § 103(a) as being unpatentable over Andoh et al. (U.S. Patent 6,239,077). The Examiner uses factors set forth in *Graham v John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) in support of this rejection. The Examiner concluded that it would have been *prima facie* obvious to one of ordinary skill in the art to be in possession of the instant compounds and compositions and method of use absent a showing of unexpected results and/or properties.

The Applicants have cancelled Claims 1-6 which were directed to compounds of formula (I). The rejection to Claims 1-6 is moot. The Applicants request that the rejection to Claims 1-6 be withdrawn.

While the Applicants have cancelled Claims 10 and 13-18, similar claims are being added. Furthermore, Claims 19-24 are still pending. The Applicants are also adding Claims 31-35 that are dependent on Claim 8. As such, the discussion below is for the new claims and pending Claims 19-24.

Concerning the claims directed to veterinary pharmaceutical compositions and to methods of using the veterinary pharmaceutical compositions to treat a mammal for parasites or to control parasites on or in a mammal, the Applicants respectfully disagree with the Examiner's conclusion that these claims are *prima facie* obvious to one of ordinary skill in the art.

In order for a *prima facie* case of obviousness to exist, the art must teach or suggest all of the elements of the claims. Yet, the art as cited by the Examiner does not teach and does not suggest the claimed veterinary pharmaceutical compositions and methods. Andoh et al. is limited to teaching compositions that contain certain compounds and the use of those compositions to kill pests in soil and on plants. But, Andoh et al. does not teach that one can use those compositions in or on mammals to kill or control parasites that live on or in the mammal.

Pending Claims 8, and 31-35 cover veterinary pharmaceutical compositions that are applied to a mammal and that kill a parasite that lives on or in the mammal. The claimed compositions are NOT applied to plants and the soil.

In contrast, Andoh et al. discloses compositions that are applied to soil and plants to kill insects on plants or in soil. Andoh et al. does not teach how the compositions disclosed in Andoh et al. would behave when administered to a mammal. Andoh et al. does not teach or suggest that the “Andoh” compositions, when administered to a mammal, are effective at killing the parasites that live in or on the mammal without causing toxicity or other adverse events to the mammal. Furthermore, Andoh et al. does not suggest that one can apply the “Andoh” compositions to a mammal and kill parasites that live on or in the mammal.

One of ordinary skill in the art would not know, without testing, that the veterinary pharmaceutical compositions claimed in Claims 8 and 31-35 could be administered to a mammal and kill parasites that live on or in the mammal without adversely affecting the mammal.

Furthermore, the fact that one can apply the veterinary pharmaceutical compositions claimed in Claims 8 and 31-35 to a mammal without harming the mammal and still be effective against parasites that live on or in the mammal is the surprising and unexpected result.

Pending Claims 19-24 cover methods of treating a mammal for parasites that live on or in the mammal by applying compositions containing at least one compound of formula (I) to the mammal.

Andoh et al. does not teach methods of treating a mammal for parasites that live on or in the mammal by applying the compositions disclosed in Andoh et al. to the mammal. Andoh et al. fails to teach or suggest that one can use the “Andoh” compositions to kill parasites that live on or in a mammal without harming the mammal. Andoh et al. does not teach or suggest a method of treating a mammal for parasites that live on or in a mammal by administering the “Andoh” compositions because Andoh et al. fails to teach or suggest that the “Andoh” compositions, when administered to a mammal, are effective at killing the parasites that live in or on the mammal without causing toxicity or other adverse events to the mammal.

One of ordinary skill in the art would not know, without testing, the method of treating a mammal for parasites that live on or in the mammal by applying the veterinary pharmaceutical compositions of Claim 8 would effectively kill parasites that live on or in the mammal without adversely affecting the mammal.

Furthermore, the fact that the method of applying the veterinary pharmaceutical compositions of Claim 8 effectively kills parasites that live on or in the mammal without adversely affecting the mammal is the surprising and unexpected result.

Pending Claims 25-30 cover the methods of controlling parasites that live on or in the mammal by applying compositions containing at least one compound of formula (I) to the mammal.

Andoh et al. does not teach the methods of controlling parasites that live on or in the mammal by applying the compositions disclosed in Andoh et al. to the mammal. Andoh et al. fails to teach or suggest that one can use the "Andoh" compositions to control parasites that live on or in a mammal without harming the mammal. Andoh et al. does not teach or suggest a method of controlling parasites that live on or in a mammal by administering the "Andoh" compositions because Andoh et al. fails to teach or suggest that the "Andoh" compositions, when administered to a mammal, are effective at controlling the parasites that live in or on the mammal without causing toxicity or other adverse events to the mammal.

One of ordinary skill in the art would not know, without testing, the method of controlling parasites that live on or in the mammal by applying the veterinary pharmaceutical compositions of Claim 8 would effectively control the parasites that live on or in the mammal without adversely affecting the mammal.

Furthermore, the fact that the method of applying the veterinary pharmaceutical compositions of Claim 8 effectively controls parasites that live on or in the mammal without adversely affecting the mammal is the surprising and unexpected result.

The Applicants point out that one of ordinary skilled in the art of plant and soil insecticides would understand that one cannot predict in advance how a mammal would handle the administration of the claimed veterinary pharmaceutical compositions to it. Prior to conducting experiments, one would not know if the claimed veterinary pharmaceutical compositions would kill the mammal. Prior to conducting experiments, one would not know if mammal would metabolize or break-down the claimed veterinary pharmaceutical compositions into agents that are ineffective for the control of parasites that live on or in the mammal, or that are ineffective for the killing of the parasites that live on or in the mammal. Only through experiments could one of ordinary skill in the art know how the claimed veterinary pharmaceutical compositions would behave after administering to a mammal.

It is well known to a person of ordinary skill in the art that the conditions required for a composition to be use as an endo- and ecto-parasiticide for warm-blooded animals are entirely different from those for plants. For example, while the amount of pesticide applied on plants is relatively unimportant (and is mainly considered in connection with costs), for a parasiticide to be acceptable for use in/or a mammal, this factor usually plays a key role, because an overdose can kill the mammal. Furthermore, the metabolism of an endo- or ecto-parasiticide is of great

importance because of the potential toxicity of the metabolites to the mammal, and to humans, if the treated animal is part of the human food chain. In contrast with plant pesticides this toxicity of the compositions is essentially considered with regard to potential environmental dangers and, therefore, requires less stringent approval conditions. Furthermore, the routes of attack of the parasitocides in and on the warm-blooded animal body against the pests are usually clearly different from that on plants, which demands different applicatory measures. Because of the different application modes, there are totally different stability requirements for the respective compositions. Compare, for example, the conditions in the blood fluid or body fat with those in the plant juice. In short, the fact that a compound is a useful pesticide for plants does by no means allow the conclusion that it is also useful within a composition for use in a completely different area.

Because one of ordinary skilled in the art could not know *apriori* how the mammal would react to the claimed veterinary pharmaceutical compositions, it is not *prima facie* obvious that the claimed veterinary pharmaceutical compositions would be suitable for administering to a mammal. It also is not *prima facie* obvious that one can use the claimed veterinary pharmaceutical compositions for the control of parasites on or in a mammal. It is also not *prima facie* obvious that one can treat a mammal with one of the claimed veterinary pharmaceutical compositions to effectively kill the parasites within or on the mammal.

As such, Applicants respectfully believe that the Examiner's rejection of Claims 8 and 19-23, along with an expected rejection of Claims 24-35, is incorrect. Applicants respectfully request that the Examiner withdraw the rejection of Claims 8 and 19-23.

The Examiner rejected Claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Andoh et al. The Examiner believes that the Claim 7 are drawn to a process for preparing insecticidal compounds by reacting corresponding amino compound with carbonyl compound. The Examiner believes that Andoh et al. teaches the preparation of aminoacetonitrile compounds.

The Applicants disagree with the Examiner's rejection of Claim 7. However, the Applicants are canceling Claim 7 at this time, without prejudice to pursue the claims in a later application.

As such, the rejection of Claim 7 is moot. Applicants request the withdrawal of this rejection.

In view of the foregoing discussion, Applicants believe that Applicants have overcome the Examiner's rejections. Applicants kindly request that the Examiner withdraw the rejections and allow the claims.

If a telephone interview would be of assistance in advancing the prosecution of this application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below with the goal of agreeing on allowable subject matter.

The Commissioner is authorized to deduct any other fee necessary to keep this application pending, from Deposit Account 19-0134.

Respectfully submitted,

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